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| <p>(54) Title: BREATH TESTING APPARATUS</p> <div data-bbox="292 1134 1282 1512"></div> <p>(57) Abstract</p> <p>This invention consists in breath testing apparatus (10) comprising a breath tube (11), a fuel cell housing (12) incorporating a pump system (12a), a fuel cell (13), a control and computational unit (14) and display (15). A thermistor (22) is provided to detect the temperature of the housing (12) during measurement and the unit (14) compensates the fuel cell output in accordance with the detected temperature.</p> | | |

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Breath Testing Apparatus

This invention relates to breath testing apparatus for detecting volatile components, such as ethanol, in a subject's breath by oxidising them in a fuel cell.

5 Such apparatus is frequently used out in the open and may therefore have to operate in a wide range of temperatures. It is known that the fuel cell response is affected by temperature and attempts have been made to overcome this variation by heating the fuel cell so that it
10 sits at or above a predetermined temperature by using thermistor control. However, this approach can cause problems both due to signal noise created by the heater and because it is difficult for the batteries in portable devices to supply sufficient current to run both the heater
15 and the electronics associated with the fuel cell during the actual measurement process.

 According to one aspect the present invention consists in breath testing apparatus including a fuel cell for producing an output signal, a housing for the fuel cell, a
20 breath sampling means connected to the housing for drawing a breath sample into the fuel cell, a thermistor for detecting the temperature of the housing, compensation means for correcting the output signal of the fuel cell in accordance with the temperature detected by the thermistor
25 and means for displaying the corrected signal.

 The apparatus may further include a heater, disposed within the housing, a thermistor for controlling the heater to maintain a part of the housing, adjacent the fuel cell,

at or above a predetermined temperature and means for disabling the heater during the operation of the fuel cell. The thermistor for controlling the heater may also constitute the thermistor for detecting the temperature of the housing. The heater may be in the form of a coil or disc and the temperature-controlling thermistor may be disposed at or adjacent the centre of the coil or disc.

The compensation means may include means for computing the corrected output in accordance with the following formula:

$$BAC_c = BAC_A \times \frac{A}{B + Cx - Dx^2}$$

wherein BAC_c is the corrected Breath Alcohol Concentration

BAC_A is the actual Breath Alcohol Concentration measured by the fuel cell;

A is the concentration of the ethanol solution used to calibrate the fuel cell;

B, C+D are constants characteristic of the fuel cell being used and of its housing; and

x is the temperature detected.

From another aspect the invention consists in a method of operating a breath testing apparatus having a fuel cell in a fuel cell chamber, including detecting the temperature of the fuel cell chamber at the time the fuel cell is operational, calculating a correction factor in accordance with the temperature, applying the correction factor to the output of the fuel cell and displaying the corrected output.

The correction factor may be:

$$\frac{A}{B+Cx-Dx^2}$$

wherein A is the concentration of the ethanol solution used
to calibrate the fuel cell;

B, C and D are constants characteristic of the fuel
5 cell being used and of its housing; and
x is the temperature detected.

The method may include the step of calibrating the fuel
cell with a "wet" standard (e.g. one in which the
calibration gas is an ethanol vapour generated by bubbling
10 as though an ethanol standard) and the fuel cell may be
heated. In this latter case the heater may be switched off
when or just before a sample is supplied to the fuel cell.

From a further aspect the invention consists in a
method of calibrating a breath testing apparatus having a
15 fuel cell including supplying a "wet" standard and
compensating the resultant output of the fuel cell in
accordance with the temperature of the fuel cell or a
housing containing it.

Although the invention has been defined above it is to
20 be understood that it includes any inventive combination of
the features set out above or in the following description.

The invention may be performed in various ways and a
specific embodiment will now be described by way of example
with reference to the accompanying drawing which is a
25 schematic diagram of breath testing apparatus.

Referring to the drawing, the breath testing apparatus, generally indicated at 10, comprises a breath tube 11; a fuel cell housing 12, incorporating a pump system 12a of the type made by Lion Laboratories Plc and supplied, for example, in their 400 Series machines for drawing a breath sample from the tube into the housing; a fuel cell 13; a control and computational unit 14 and a display 15. On the outside of fuel cell 13 there is a heater disc 17 and a thermistor 18 is disposed approximately at the centre of the heater 17. Both of these are connected to a power supply 14a associated with the unit 14.

As is well-known the user blows into the breath tube 11 in the direction marked by the arrow A and after a predetermined time of breath being blown above a predetermined pressure, a sample of breath is sucked down by the pump 12a into the housing 12 through a side port 19 formed in the breath tube 11 and an inlet 20 formed on the housing 12. This sample is then sucked into the fuel cell at 21. The fuel cell 13 oxidises any ethanol in the sample, in a conventional manner, and its electrical output is fed to the control and computational unit 14.

It has been determined that the output of the fuel cell varies with temperature and this can be significant because the apparatus may be used in temperatures in a range which may be typically -5°C to 40°C. The traditional approach to this is to heat the fuel cell housing, but this has the disadvantages previously noted. In the applicant's arrangement therefore a temperature sensing thermistor,

arrangement therefore a temperature sensing thermistor, which is either constituted by the thermistor 18 or a distinct separate thermistor such as is illustrated at 22, is provided. This measures the housing temperature at the
5 time that the fuel cell is operational and feeds this output to the unit 14, which then corrects the fuel cell output in accordance with the measured temperature before the output is displayed digitally to show the breath alcohol content (BAC) of the user. As the heater 17 is usually switched off
10 during the operation of the fuel cell, both to prevent noise and battery drain, the thermistor 18 can provide this function for most purposes. If however it is desirable to run the heater during this operation the separate thermistor 22 is to be preferred.

15 Experiments have shown that for fuel cells of the type WR manufactured by Lion Laboratories Plc, the computational unit provides an accurate output for display if it corrects the actual output in accordance with the following formula:

$$BAC_c = BAC_A \times \frac{A}{B + Cx - Dx^2}$$

wherein BAC_c is the corrected Breath Alcohol Concentration
20 BAC_A is the actual Breath Alcohol Concentration
 A is the concentration of the ethanol solution
used to calibrate the fuel cell;

$B, C+D$ are constants characteristic of the fuel
25 cells being used and of its housing; and
 x is the temperature detected.

It is anticipated that most fuel cells will have a correction formula of a similar form, but the constants will vary depending on the fuel cell and the housing. The appropriate constants can readily be calculated by a man skilled in the art plotting the output of any particular fuel cell against temperature. It is perfectly possible with this arrangement to dispense with the heater altogether or to configure the arrangement such that the heater only operates if the fuel cell temperature is below say -5°C .

The applicants have determined that, surprisingly, there is a difference in the temperature response of such breath testing apparatus to dry calibration samples as against wet calibration samples. The dry calibration samples, which are often provided in aerosol form, provide an inaccurate representation of the performance of the fuel cell against temperature and, contrary to normal practice, temperature compensation for breath testing apparatus of this sort should be calculated using a wet standard. This is the type where the calibration gas is in equilibrium with a liquid such as water.

CLAIMS

1. Breath testing Apparatus including a fuel cell for producing an output signal , a housing for the fuel cell, a breath sampling means connected to the housing for draining
5 a breath sample into the fuel cell, a thermistor for detecting the temperature of the housing, compensation means for correcting the output signal of the fuel cell in accordance with the temperature detected by the thermistor and means for displaying the corrected signal.
- 10 2. Apparatus as claimed in Claim 1, further including a heater, disposed within the housing , a thermistor for controlling the heater to maintain a part of the housing adjacent the fuel cell at or above a predetermined temperature and means for disabling the heater during
15 operation of the fuel cell.
3. Apparatus as claimed in Claim 2, wherein the thermistor for controlling the heater also constitutes the thermistor for detecting the temperature of the housing.
- 20 4. Apparatus as claimed in Claim 2 or Claim 3, wherein the heater is in the form of a flat coil or disc and the temperature controlling thermistor is disposed at or adjacent the centre of the coil or disc.
- 25 5. Apparatus as claimed in any one of the preceding Claims wherein the compensation means includes means for computing the corrected output in accordance with the following formula:

$$BAC_c = BAC_A \times \frac{A}{B + Cx - Dx^2}$$

wherein BAC_c is the corrected Breath Alcohol Concentration

BAC_A is the actual Breath Alcohol Concentration
measured by the fuel cell;

5 A is the concentration of the ethanol solution
used to calibrate the fuel cell;

$B, C+D$ are constants characteristic of the fuel cell
being used and of its housing; and

x is the temperature detected.

10 6. Breath Testing Apparatus substantially as
hereinbefore described with reference to the accompanying
drawings.

7. A method of operating a breath testing apparatus
having a fuel cell in a fuel cell chamber including
15 detecting the temperature of the fuel cell chamber at the
time the fuel cell is operational, calculating a correction
factor in accordance with the temperature, applying the
correction factor to the output of the fuel cell and
displaying the corrected output.

20 8. A method as claimed in Claim 7, wherein the
correction factor is

$$\frac{A}{B + Cx - Dx^2}$$

wherein A is the concentration of the ethanol solution used
to calibrate the fuel cell;

25 B, C and D are constants characteristic of the fuel
cell being used and of its housing; and

x is the temperature detected.

9. A method as claimed in Claim 7 or Claim 8, including calibrating the fuel cell with a "wet" standard.

10. A method as claimed in any one of Claims 7 to 9
5 wherein the fuel cell is heated.

11. A method as claimed in Claim 10, wherein the heater is switched-off when or before a sample is supplied to the fuel cell.

12. A method of operating breath testing apparatus
10 substantially as hereinbefore defined.

13. A method of calibrating a breath testing apparatus having a fuel cell including supplying a "wet" standard and compensating the resultant output of the fuel cell in accordance with the temperature of the fuel cell or a
15 housing containing it.

14. A method of calibrating substantially as hereinbefore defined with reference to the accompanying drawings.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 96/01419

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 G01N33/497

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

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IPC 6 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X Y | US,A,4 749 553 (LOPEZ ET AL.) 7 June 1988 see the whole document --- | 1,7,9,13 2,10,11 |
| Y | WO,A,92 22813 (ALCOHOL MEASURING EQUIPMENT PTY. LIMITED) 23 December 1992 see the whole document --- | 10,11 |
| Y | US,A,3 877 291 (HOPPESCH) 15 April 1975 see column 2, line 54 - column 12, line 61; figures --- | 2,11 |
| A | US,A,3 966 579 (CHANG ET AL.) 29 June 1976 see column 3, line 28 - column 9, line 2; figures --- -/-- | 2,11 |

☒ Further documents are listed in the continuation of box C.

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European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | SENSORS AND ACTUATORS B, vol. b13, no. 1/3, May 1993, LAUSANNE CH, pages 256-258, XP000382709 N.P. MAKSIMOVICH: "DEVICE WITH SEMICONDUCTOR GAS SENSOR FOR ALCOHOL VAPOUR DETECTION IN AN EXHALED AIR SAMPLE" see page 256, left-hand column, paragraph 2 - page 257, left-hand column, paragraph 1; figure 1 ----- | 1-14 |
| A | DE,A,34 03 450 (JACK SIMON CARMEL) 9 August 1984 see the whole document ----- | 1-14 |

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 96/01419

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|--|--|
| US-A-4749553 | 07-06-88 | AU-A- 1547188 WO-A- 8808085 US-A- 4874299 | 04-11-88 20-10-88 17-10-89 |
| WO-A-9222813 | 23-12-92 | NONE | |
| US-A-3877291 | 15-04-75 | AU-A- 5833773 CA-A- 997585 DE-A- 2340678 FR-A- 2196718 GB-A- 1398190 JP-C- 1128085 JP-A- 49109091 JP-B- 56052258 SE-B- 409371 | 23-01-75 28-09-76 28-02-74 15-03-74 18-06-75 24-12-82 17-10-74 10-12-81 13-08-79 |
| US-A-3966579 | 29-06-76 | NONE | |
| DE-A-3403450 | 09-08-84 | AU-B- 565207 AU-A- 2398484 CA-A- 1218734 FR-A- 2585082 GB-A,B 2139387 JP-A- 59184032 NL-A- 8400300 SE-B- 456811 SE-A- 8400511 US-A- 4592443 | 10-09-87 02-08-84 03-03-87 23-01-87 07-11-84 19-10-84 03-09-84 07-11-88 02-08-84 03-06-86 |